**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | SEPTRIMED SUSPENSION | | REF. NO: NDQA201509381 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each 5mL contains Trimethoprim BP 40 mg, Sulphamethoxazole BP 200 mg and Flavoured vehicle to 5 mL. | |
| **BATCH NO.:** M11474 | **PRESENTATION:** | Light pink coloured, suspension for oral administration, contained in a 50 mL translucent plastic bottle. | |
| **MGF. DATE:** Nov. 2014 | **MANUFACTURER:** | MEDIVET Products Ltd, | |
| **EXP. DATE:** Oct. 2017 | **ADDRESS:** | P.O.Box 47951-00100 G.P.O., Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| COT/05/17.03.2015/00355 | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count Method | BP 2016 Vol. V Appendix XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL Total Combined Yeasts/Moulds Count (TYMC) NMT 20 CFU/mL | < 200 TAMC CFU/mL < 20 TYMC CFU/mL | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5397-5398 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.6 and 9.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5397-5398 | 90.0 - 110.0% | Sulphamethoxazole 95.5% (RSD = 1.4%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5397-5398 | 90.0 - 110.0% | Trimethoprim 95.0% (RSD = 1.5%; n=9) | **COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 5397-5398 | 5.0 - 6.5 | 5.6 | **COMPLIES** |

**CONCLUSION:** The product complies with the specifications for the tests performed.

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| ANALYST: | FRANCIS NAULA |  | DATE:22-01-2016 |
| ANALYST: | JOYFRIDA CHEPCHUMBA |  | DATE:22-01-2016 |
| REVIEWER: | EMMANUEL TANUI |  | DATE:22-01-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-26-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-26-2016 |